Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 13-02892-217

Healthcare Inspection

Alleged Mismanagement in the Cardiac Catheterization Laboratory VA Maryland Health Care System Baltimore, Maryland

July 15, 2014

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection in response to allegations regarding the cardiac catheterization laboratory (CCL) at the Baltimore VA Medical Center (facility), Baltimore, MD. The allegations related to mismanagement of CCL patient emergencies and CCL staffing.

We did not substantiate the allegation that a patient died because CCL staffing was insufficient to perform an urgent case and leadership delayed transferring the patient to the University of Maryland medical center. The patient's providers, in consultation with the patient's family, decided not to perform an urgent catheterization because of the patient's unstable status, not because of CCL staffing or other administrative considerations.

We did not substantiate that the CCL nurse manager, intensive care unit (ICU) nurses, and Anesthesia Service ignored CCL staff requests for help during a cardiac emergency. We found no documentation of CCL staff calling a code blue in the patient's case other than in an ICU nurse's note. Staff we interviewed reported that they sometimes encountered delays in response for code blue and anesthesia assistance, but the nurse manager and ICU staff generally responded timely to CCL staff's requests for help.

We did substantiate that CCL staff were correctly told not to call the rapid response team for help. The rapid response team is limited to responding to inpatient situations only, and the CCL is an outpatient clinic.

We did not substantiate that the facility did not follow "standard of care requirements" since there are no definitive national or VHA standards for minimal staffing of the CCL. However, we found that the facility did not consistently meet national and local policy requirements for staffing during CCL procedures involving moderate sedation. Changes implemented at the facility in April 2013 required two registered nurses for all CCL procedures. We did not substantiate that nurse managers mismanaged or ignored requests for additional staff coverage in the CCL. The facility acknowledged ongoing efforts to evaluate the cost-benefit of CCL in-house operations because of low volume of procedures in the CCL.

Incidental to our inspection, we found that staff were unclear about the roles of the code blue and rapid response teams, as well as the process for obtaining anesthesiologist assistance in the event of an emergency in the CCL.

We recommended that the System Director ensure that:

- Nurse staffing is appropriate for the volume and types of procedures performed in the cardiac catheterization laboratory and that the requisite nurse competencies are maintained.

- The policies and procedures regarding the rapid response team, code blue team, and Anesthesia Services are updated as needed to reflect desired practices for managing cardiac catheterization laboratory emergencies.

- The staff receive training on updated policies and procedures regarding the rapid response, code blue team and Anesthesia Services.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with our recommendations and provided an acceptable action plan. (See Appendixes B and C, pages 14–17 for the Directors' comments.) We will follow up on the planned actions until they are completed.

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection in response to allegations regarding the cardiac catheterization laboratory (CCL) at the Baltimore VA Medical Center (facility), Baltimore, MD. The purpose of the review was to determine if the allegations had merit.

Background

Facility Profile. The VA Maryland Health Care System (system) consists of three campuses—the Baltimore VA Medical Center, the Perry Point VA Medical Center, and the Loch Raven VA Community Living & Rehabilitation Center—and six community based outpatient clinics. The system has affiliations with the University of Maryland School of Medicine (University) and other local colleges and universities and is part of Veterans Integrated Service Network (VISN) 5. The facility has 137 beds and provides a range of acute medical, surgical, specialty, and outpatient services.

Cardiac Catheterization. The American Heart Association describes cardiac catheterization as follows.

> Cardiac catheterization (cardiac cath or heart cath) is a procedure to examine how well [the] heart is working. A thin, hollow tube called a catheter is inserted into a large blood vessel that leads to [the] heart… The procedure is done in a hospital cardiac catheterization (cath) lab. Before the cath procedure, a nurse will put an IV (intravenous) line into a vein in [the] arm so [the patient] can get medicine (sedative) to help…relax, but…be awake and able to follow instructions during the procedure…[1]

Using special x-ray machines and other equipment, CCL staff can perform several technical procedures, including:

- Angiography, which involves injection of a dye that allows blood vessels to be seen on X-rays.
- Ventriculography, a test to assess how well blood is flowing through the heart's chambers.[2]
- Percutaneous coronary intervention (PCI) or angioplasty that uses a catheter to clear a narrowed or blocked artery.[3]

[1] Cardiac Catheterization, https://www.heart.org/HEARTORG/Conditions/HeartAttack/SymptomsDiagnosisofHeartAttack/Cardiac-Catheterization_UCM_451486_Article.jsp, Accessed February 11, 2014.
[2] Nuclear Ventriculography, http://www.nlm.nih.gov/medlineplus/ency/article/003822.htm, Accessed March 7, 2014.

- Placement of small mesh tubes called stents that treat narrow or weak arteries and drug-eluting stents (DES) that release the medication and prevent blockages in the artery.[4]
- Insertion of pacemakers.[5]

To perform such procedures, CCL team members receive training in procedures, radiation safety, medications, moderate sedation, and other specialized aspects of cardiology.[6]

In 2011, Veterans Health Administration (VHA) had 76 CCLs that collectively performed procedures on 42,157 patients. As part of a national quality initiative begun more than a decade ago, VHA created a national CCL data repository called the Clinical Assessment Reporting and Tracking – Catheterization Laboratory (CART-CL) program that integrated software for data entry, reporting, data flow, and electronic health record (EHR) interface.[7]

The facility's CCL operates on business days, typically begins procedures at 9:00 a.m., and finishes by late afternoon. A Medical Director and staff, including residents and fellows affiliated with the University, provide the physician support for the facility's CCL. The facility also employs two full-time registered nurses (RNs) and two full-time technicians for its CCL. Patients with complications, urgent needs, or those that require cardiac catheterizations during non-business hours are sent to the University's CCL, located across the street from the facility.

VHA has not published a standard of care or staffing requirements for CCLs, and non-VHA professional articles and statements offer limited guidance. For example, the American College of Cardiology Foundation Task Force on Expert Consensus stated in 2012, "The type and number of nursing personnel required in the catheterization laboratory depend on the laboratory caseload and types of procedures performed." Another professional organization, the Society of Invasive Cardiovascular Professionals (SICP), published the 2010 Revised Position Statement – Staffing in the Cardiac Catheterization and EP Lab, which states:

> There are three primary roles of the cardiovascular invasive specialist [CCL staff]: hemodynamic monitoring/documenting, circulating, and

[3] Cardiac Catheterization, https://www.heart.org/HEARTORG/Conditions/HeartAttack/SymptomsDiagnosisofHeartAttack/Cardiac-Catheterization_UCM_451486_Article.jsp, Accessed February 11, 2014.
[4] National Heart, Lung, and Blood Institute, What Is a Stent? http://www.nhlbi.nih.gov/health/health-topics/topics/stents/, Accessed November 20, 2013.
[5] A pacemaker is a small device that sends electrical pulses to the heart to help the heart beat at a normal rate. http://www.nhlbi.nih.gov/health/health-topics/topics/pace/, Accessed February 11, 2014.
[6] 2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update. *J Am Coll Card*. 2012; 59 (24): 2224-2305.
[7] The VA Cardiovascular Assessment, Reporting, and Tracking System for Cath Labs, presentation by John S. Rumsfeld, MD PhD, Clinical Director, CART-CL, Denver VA Medical Center, http://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/vci-041707.pdf.

> scrubbing…. For diagnostic or interventional procedures staffed by only one physician, at least three non-physician personnel should be present. When there is more than one physician scrubbed for the procedure, a minimum of two non-physician personnel are recommended for monitoring/documentation and circulating for the procedure. For unstable patients, or complex interventional procedures involving multiple technologies, additional staffing may be needed.[8]

Allegations. VA OIG's Hotline Division received several general allegations in April 2013, followed by more specific information in July. The complainant(s) cited several examples to support that CCL patient emergencies were mismanaged:

- The death of a patient (Patient 1) who did not have an urgent cardiac catheterization because the nurse manager (NM) did not ensure sufficient nursing staff to perform the catheterization and facility administration delayed the patient's transfer to the University.

- The case of a patient (Patient 2) who experienced a cardiac emergency in the CCL while a CCL RN worked alone (without a second RN); as the patient's condition worsened, the NM, intensive care unit (ICU) RNs, and Anesthesia Service ignored CCL staff requests for help. Later, when the CCL staff called a code blue,[9] help arrived promptly but the patient died in an ICU.

- Threats of an administrative action against a CCL RN who called the rapid response team[10] for help during a CCL emergency.

In addition, CCL RN staffing was allegedly mismanaged because the NM:

- Did not consistently staff the CCL with two RNs as required by standards of care.

- Detailed insufficiently trained RNs to work in the CCL, including a newly selected CCL RN and a gastrointestinal (GI) laboratory RN who did not have CCL training or experience.

- Asked a pregnant RN to assist the CCL and risked exposing her to radiation.

- Ignored requests for additional nursing staff resulting in CCL procedures often being performed with only one RN.

[8] http://www.sicp.com/content/revised-position-statement-%E2%80%93-staffing-cardiac-catheterization-and-ep-lab.
[9] A Code Blue is an alert for the Medical Emergency Response Team to respond to all cardiopulmonary arrest medical emergencies. VAMHCS Policy Memorandum 512-ll/ECOS-036, Medical Emergency Response Team, August 2011.
[10] A rapid response team is a group of health care providers who respond quickly to assess and treat patients who are unstable or show signs of clinical distress, deterioration, or change. http://journals.lww.com/anesthesia-analgesia/pages/articleviewer.aspx?year=2010&issue=09000&article=00015&type=abstract. Accessed February 11, 2014.

Scope and Methodology

We conducted a site visit July 29–31, 2013. We reviewed industry standards related to CCLs. We reviewed VHA and local policies; committee minutes; RN training records; data from CART-CL; Patient Advocate Tracking System; and other relevant documents. We also reviewed the EHRs of selected patients treated in the facility's CCL during the timeframe of the allegations, including March 14, 2011–March 8, 2013.

We interviewed the facility's Director; Chief of Staff; Chief of Medicine Clinical Center; CCL physicians, RNs, NM, and technicians; RNs from non-CCL areas who provided coverage in the CCL; and other clinical, administrative, and quality management staff with knowledge relevant to the allegations. We also interviewed VHA's Cardiology Nurse Consultant for Patient Care Service and National Program Director for Cardiology.

Additional allegations related to retaliation issues and resource allocation were outside OHI's purview and not reviewed.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Inspection Results

Issue 1: Mismanaged CCL Patient Emergencies

Death of Patient 1. We did not substantiate that Patient 1 died because CCL staffing was insufficient to perform an urgent case and leadership delayed transferring the patient to the University.

Patient 1 was an elderly veteran who came to the facility early one morning in February 2013 for a scheduled carotid endarterectomy.[11] Shortly after arriving, he suffered a cardiac arrest.[12] A code blue was called, and the patient was intubated, shocked, and given chest compressions before transfer to the ICU around 8:00 a.m. At 10:02 a.m., the cardiology fellow documented the following in the patient's EHR.

> After the code, the patient was barely responsive with sluggish pupils and poor response to pain. […] The decision was made to hold off on a cardiac catheterization given poor neurologic response and no significant ST segment depressions or elevations on EKG [electrocardiogram].

The patient continued to decompensate and experienced other complications. Later in the morning, an ICU physician noted the following in the patient's EHR.

> Given his outpatient vfib [ventricular fibrillation][13] arrest, we secured a bed in the Shock-Trauma Center for initiation of therapeutic hypothermia. However, due to hemodynamic instability, the patient was deemed too unstable for transfer. His family was present throughout the entire morning and after careful consideration and discussion, his three daughters made the decision not to escalate care and to change his code status to DNR.... Throughout the morning, despite maximal pharmacologic hemodynamic support, the patient's blood pressure continued to drop.... He eventually passed and was pronounced dead by me and the ICU house staff at 11:24 a.m.…

When interviewed, the cardiology fellow told us that he remembered Patient 1's case very well. He recalled that because the event happened so early in the morning, he contacted the lead cardiologist to initiate plans to transfer the patient to the University's CCL. However, because the patient's status was changing, the lead cardiologist recommended that they "not rush" the patient to a CCL. The cardiology fellow said that

[11] A carotid endarterectomy is a same day surgery that reduces the risk of stroke by removing fatty build up inside a large artery in the neck. http://www.nhlbi.nih.gov/health/health-topics/topics/carend/, Accessed February 11, 2014.
[12] Cardiac arrest is a sudden loss of heart function. https://www.heart.org/HEARTORG/Conditions/More/CardiacArrest/About-Cardiac-Arrest_UCM_307905_Article.jsp, Accessed February 11, 2014.
[13] The American Heart Association describes ventricular fibrillation as "when the heart's lower chambers suddenly start beating chaotically and don't pump blood." https://www.heart.org/HEARTORG/Conditions/More/CardiacArrest/About-Cardiac-Arrest_UCM_307905_Article.jsp

he likely called the facility's CCL to check the schedule and staffing; although, he "did not expect the [facility's] CCL to be up and ready" before 9:00 a.m. Ultimately, they decided not to perform an urgent catheterization based upon the patient's unstable status and not because of administrative decisions or CCL staffing.

Case of Patient 2. We did not substantiate that NM, ICU RNs, and Anesthesia Service ignored CCL staff requests for help during a cardiac emergency.

Patient 2 was an elderly veteran who was admitted to the facility for exacerbation of chronic obstructive pulmonary disease in August 2012. At admission, the patient said he had been without medications for about 2 weeks and had thoughts of suicide. Clinicians noted that he had several diagnoses, including high blood pressure, congestive heart failure, bilateral pleural effusions,[14] and a possible myocardial infarction.[15] Cardiologists recommended that the patient undergo a cardiac catheterization.

The patient's EHR shows that on hospital day 6 at 12:18 p.m., three physicians, one RN, and two technicians initiated CCL procedures for left heart catheterization, coronary angiography, and PCI. However, EHR documentation reflects that the patient became agitated during the procedure and required intubation and a higher level of sedation. The CART-CL report vital-signs record shows that the patient's heart rate and blood pressure began to increase around 2:51 p.m. and that an anesthesiologist arrived to the room at 3:40 p.m. The CART-CL report also showed that the patient developed a potentially fatal rapid heartbeat and that staff administered three defibrillator shocks between 3:53–4:08 p.m. in an effort to stabilize him. Subsequent CART-CL records show that CCL staff placed two left anterior descending coronary artery stents before transferring the patient to the cardiac ICU at 5:46 p.m.

The patient's EHR shows that while in the ICU, the patient was on a ventilator and staff continued to manage his lung and cardiac conditions. According to the EHR, the patient began breathing on his own after several days and was transferred from the ICU to an acute care unit on hospital day 14. At this time, a physician noted in the EHR that the patient understood that his illness was serious and said that he "did not want CPR [cardio-pulmonary resuscitation], intubation, or defibrillation if his heart were to stop." On hospital day 16, the patient died.

We did not substantiate the allegation that the NM, ICU, or Anesthesia Service did not respond to CCL staff requests for help and that help did not arrive until the CCL staff called a code blue. While a cardiac ICU RN noted in the patient's EHR that a code blue was called during the procedure, there is no other documented EHR reference to a code blue or request for help. Further, the CART-CL record does not mention requests for help or a code blue call, and the facility had no post-code blue evaluation, incident report, or close-call report related to this case. Staff we interviewed did not recall the

[14] Pleural effusion refers to fluid in the lung. http://www.medicinenet.com/script/main/art.asp?articlekey=114975&pf=3&page=1, Accessed March 20, 2014.
[15] Myocardial infarction is also known as a "heart attack" and refers to death of the heart muscle. http://www.webmd.com/heart-disease/understanding-heart-attack-basics Accessed March 20, 2014.

specific circumstances of Patient 2's case but acknowledged that they sometimes encountered delays in response for code blue and anesthesia assistance. In contrast, they reported that the NM and ICU staff generally responded timely to CCL staff's requests for help.

Threats for Calling Rapid Response Team. We substantiated this allegation; CCL nursing staff reported that after one incident, nursing leaders threatened future administrative action should the CCL staff call the rapid response team for help. Facility leaders told us that, according to local policy, the rapid response team is limited to responding to inpatient situations only. Since the CCL is an outpatient clinic, CCL staff were directed to call a code blue for emergencies.

We conducted a general review of patient-safety related reports and other documents to further evaluate the oversight and management of the CCL. We did not find evidence to indicate improper administrative interventions. Since 2010, one CCL-related patient death has occurred for which the facility conducted several thorough reviews, including a code blue evaluation. The Invasive Procedure Committee regularly reviews CCL procedures and looks for adverse events. To date, there have been no circumstances to warrant further investigation or action nor have there been complaints registered through the Patient Advocate Tracking System.

Issue 2: CCL RN Staffing

Two RN Requirement. We did not substantiate the allegation that the facility did not follow "standards of care" regarding CCL staffing policies since there are no definitive national or VHA standards for minimal staffing of the CCL. However, we found that prior to April 2013, staffing did not consistently meet VHA staffing directives for CCL procedures involving moderate sedation.

The facility's CCL full-time staff included two RNs and two technicians. When one RN was absent, the NM would sometimes assign an RN from an ICU or GI clinic to assist in the CCL. On occasion, only one RN was on duty during procedures.

At the time of our review, VHA had not published standards of care or staffing requirements for CCLs. VHA's Cardiology Nurse Consultant for Patient Care Services and the National Program Director for Cardiology told us that staffing depends on the individual facility, its purpose, clinicians, and procedures offered. They expect minimum CCL staffing to include a physician, an RN, and a technician. However, they stated that a second RN is advisable in CCL cases that are complicated or require moderate sedation.

The facility's moderate sedation policy mirrored the VHA moderate sedation directive and states, "Healthcare providers who are granted privileges to administer…and monitor patients during moderate sedation/analgesia can be a licensed registered nurse or advanced practice nurse…. During the [moderate sedation] procedure the [RN] will continually monitor the patient. This individual will not have any other responsibilities that could interfere with continual monitoring of the patient."

We reviewed 10 cases (other than the two previously discussed) named in the allegation as problematic. In seven of these cases, the records showed that one RN, working alone with the physicians and technicians, provided moderate sedation medications and monitored the patients. Without a second RN, the RN would have to stop monitoring the patient to carry out orders for the administration of other medications, including intravenous medications.

Table 1 in Appendix A summarizes the cases, including procedures performed, total number of CCL staff present, and the patients' outcomes.

In mid-April 2013, the facility's CCL Medical Director implemented a standard requiring two RNs be present during all CCL procedures. To meet the new two-RN staffing requirement for all CCL procedures, NMs sought RN volunteers to provide CCL coverage when needed. Further, the CCL NMs and Medical Director recognized the need for and planned refresher training for those RNs who were not comfortable with some CCL functionality because they did not regularly perform duties in the CCL.

CCL RN Training and Experience. We did not substantiate that the NM detailed insufficiently trained and/or inexperienced nurses to assist in the CCL.

In the allegation, the complainant identified instances involving three different patients in which a newly selected RN worked in the CCL without sufficient training, orientation, and experience. We reviewed each case and found no evidence of provider-perceived problems or documented patient complications related to nursing care. In each case, one or two other RNs were present in the CCL, each with varied levels of experience. Training records indicated that the new CCL staff RNs received training and orientation commensurate with expected CCL duties.

We reviewed the training and competency folders for the ICU and GI laboratory nursing staff who were assigned intermittently to the CCL and found that each RN had acceptable training, including training for the monitoring of patients receiving moderate sedation, as well as certification in advanced cardiac life support. In addition, most staff members who were assigned intermittently to the CCL told us that they believed that they had adequate training and did not feel that patient safety was jeopardized.

The allegation included a statement that the NM sent one GI laboratory RN with no facility-specific CCL experience to assist in the CCL; however, this RN described having extensive prior CCL and cardiac surgery experience in a non-VA hospital.

Pregnant RN Detailed to the CCL. We did not substantiate that a pregnant RN who was asked by the CCL NM to work in the CCL would have been in danger from radiation had she been pulled to the CCL.

We confirmed that the NM asked a pregnant ICU RN to work one case in the CCL. However, the RN indicated that, although she was asked, she did not work in the CCL at any point during her pregnancy. Additionally, according to the National Center for Biotechnology Information's PubMed website, "Current data do not suggest a significant increased risk to the fetus of pregnant women in the cardiac catheterization laboratory

and thus do not justify precluding pregnant [individuals] from performing procedures in the cardiac catheterization laboratory. However, radiation exposure among pregnant physicians should be properly monitored and adequate radiation safety measures are still warranted."[16] The NM stated that the pregnant RN would have been provided radiation protective wear and would not have been required to stay.

NM Response to Requests for Additional CCL Nursing Staff. We did not substantiate that the CCL NM ignored requests for additional nursing staff resulting in CCL procedures often being performed with only one RN.

The majority of the facility's CCL cases were considered low risk procedures, and according to the facility's CCL medical director, an average patient case took about 2½ hours to complete. As described above, the CCL NM arranged additional nursing help for cases by authorizing overtime or assigning RNs from ICUs, the GI lab, or other specialized areas, when possible. However, staff we interviewed told us that there were times when, for staffing reasons, the NMs of ICU and other areas could not allow RNs to be reassigned to the CCL upon request by the CCL's NM.

Other Challenges with CCL Staffing. The facility's leadership had other challenges with CCL staffing. For example, the facility's CART-CL reports for the past 3 fiscal years show an average workload volume of approximately one patient per workday—less than half of VHA's nationally reported average. Between October 1, 2012 and April 15, 2013 (before the requirement for two RNs began), 27 workdays (20 percent) had no CCL patient cases or activities. Following the two-RN requirement, from April 16 through June 26, 2013, 19 workdays (38 percent) had no CCL patient cases. Although dedicated CCL RNs have other duties related to consults, equipment, and supply management, NMs detailed the CCL staff members to work in other areas, such as the GI Laboratory on the days without CCL cases. According to staff we interviewed, these details were a significant cause of staff dissatisfaction.

Recognizing the declining CCL workload over recent years, facility managers and leaders reported that they evaluated other options, including closing the CCL and using fee-based CCL services. They found that keeping the facility's CCL open was a service they felt was important to maintain for the veterans and believed it to be cost-advantageous in comparison with sending patients to the University's CCL.

Issue 3: Other Concerns Regarding Response to CCL Emergencies

Incidental to our inspection, we found that staff were unclear about the roles of the code blue and rapid response teams, as well as the process for obtaining anesthesiologist assistance in the event of an emergency in the CCL.

CCL providers told us that they usually are able to detect the early signs of a decompensating patient and rarely need a full code blue team response. Instead, they usually need an anesthesiologist to manage the patient's airway and sedation level.

[16] SCAI consensus document on occupational radiation exposure to the pregnant cardiologist and technical personnel, http://www.ncbi.nlm.nih.gov/pubmed/21061249, Accessed March 7, 2014.

Therefore, the CCL providers have often instructed the CCL staff to call Anesthesia Service directly to request assistance. However, the Chief of Anesthesia Service told us that he has discouraged direct calls to Anesthesia Service and expects that facility staff call a code blue or the rapid response team instead. Facility leaders have advised CCL and other outpatient staff to call a code blue for emergencies because facility policy limits the rapid response team to inpatient situations, while the CCL is considered an outpatient unit.

Conclusions

We did not substantiate that Patient 1 died because CCL staffing was insufficient to perform an urgent case and leadership delayed transferring the patient to the University. According to the EHR and the cardiology fellow's report, the decision to not perform a cardiac catheterization on Patient 1 was based on the patient's medical status and no other reasons. We also did not substantiate the allegation that help was requested for Patient 2 but did not arrive until the CCL staff called a code blue. Medical and administrative records had insufficient documentation to support that help was either requested or delayed.

We did substantiate that after one incident, nursing leaders threatened future administrative action should the CCL staff call the rapid response team for help. By local policy, the rapid response team is limited to responding to inpatient situations only, and because CCL is an outpatient clinic, staff should call a code blue for emergencies.

VHA has not published a standard of care or staffing requirements for CCLs; therefore, we did not substantiate that the facility did not follow "standard of care requirements." Although the facility did not consistently meet VHA's directive for two RNs to be present during CCL procedures involving moderate sedation, changes implemented in April 2013 required two RNs for all CCL procedures. We did not substantiate that the CCL NM mismanaged or ignored requests for additional staff coverage in the CCL. The facility acknowledged ongoing efforts to evaluate the cost-benefit of CCL in-house operations because of low volume.

In addition to the allegations in the complaint, our inspection revealed that some facility staff were unclear regarding the policy and roles of the code blue and rapid response teams as well as accessibility of anesthesiologists. Some staff were also unaware that anesthesiologists are part of the code blue team but not the rapid response team.

Recommendations

Recommendation 1. We recommended that the System Director ensure that nurse staffing is appropriate for the volume and types of procedures performed in the cardiac catheterization laboratory and that the requisite nurse competencies are maintained.

Recommendation 2. We recommended that the System Director ensure that the policies and procedures regarding the rapid response team, code blue team, and

Anesthesia Services are updated as needed to reflect desired practices for managing cardiac catheterization laboratory emergencies.

Recommendation 3. We recommended that the System Director ensure that the staff receive training on updated policies and procedures regarding the rapid response, code blue team and Anesthesia Services.

Appendix A

Table 1. Alleged Insufficiently Staffed CCL Cases

Case	Date	Planned Procedures	Actual Procedures	RNs	Radiology Technicians	Physicians	Total CCL Staffing	24-hour outcome per physician's note
a	6/6/11	• Left heart catheterization • Coronary angiography	• Left heart catheterization with ventriculography • Coronary angiography • DES stent placement	1	2	2	5	"No complications"
b	6/9/11	• Left heart catheterization • Coronary angiography	• Left heart catheterization • Coronary angiography • Intravascular ultrasound • DES stent placement	1	2	3	6	"currently stable" after an allergic reaction to contrast
c	8/31/2011	• Left heart catheterization • Coronary angiography	• Left Heart Catheterization • Coronary Angiography • DES stent placement	1	2	2	5	"no events overnight"
d	12/6/11	• Left heart catheterization • Coronary angiography	• Left heart catheterization with ventriculography • Coronary angiography	1	2	2	5	"[…] some groin pain […] otherwise doing well."
e	8/28/12	• Left heart catheterization • Coronary angiography • PCI	• Left heart catheterization • Coronary angiography • Iliac angiography • Vascular occlusive device placement • Stent placement	1	2	2	5	"no complications"
f	10/15/12	• Left heart catheterization • Coronary angiography • Bypass graft angiography	• Left heart catheterization with ventriculography • Coronary angiography • Internal mammary artery bypass graft angiography • Saphenous vein graft angiography • Pacemaker insertion • DES stent placement	1	2	2	5	"Procedure without any complication"
g	1/22/13	• Left heart catheterization • Left ventricular angiography • Coronary angiography	• Left heart catheterization • Coronary angiography • Iliac angiography • Vascular occlusive device placement • DES stent placement	2	0	3	5	"Successful" (discharged same day)
h	1/24/13	• Left heart catheterization • Left ventricular angiography • Coronary angiography	• Left heart catheterization • Coronary Angiography • Iliac angiography • Vascular occlusive device placement	2	0	3	5	"Cath revealed minimal [disease]" (discharged the same day)

Table 1. Alleged Insufficiently Staffed CCL Cases

Case	Date	Planned Procedures	Actual Procedures	RNs	Radiology Technicians	Physicians	Total CCL Staffing	24-hour outcome per physician's note
i	3/8/13	• Left heart catheterization • Coronary angiography	• Left heart catheterization • Right heart catheterization • Vascular occlusive device placement • Iliac[17] angiography • DES stent placement • Coronary angiography	1	1	2	4	"Doing well post-procedure"
j	6/27/13	• Right heart catheterization • Pericardio-centesis[18]	• Right heart catheterization • Interpretation of cardiac output measurements	2	2	2	6	"stable" (discharged the next day)

Source: VA OIG

[17] The iliac is an artery that originates from the aorta (a large and major blood vessel coming from the heart). http://www.healthline.com/human-body-maps/common-iliac-artery, Accessed March 8, 2014.
[18] "Pericardiocentesis is a procedure that uses a needle to remove fluid from the pericardial sac, the tissue that surrounds the heart." http://www.nlm.nih.gov/medlineplus/ency/article/003872.htm, Accessed March 8, 2014.

Appendix B

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: June 27, 2014

From: Director, VA Capital Health Care Network (10N5)

Subject: **Healthcare Inspection – Alleged Mismanagement in the Cardiac Catheterization Laboratory, VA Maryland HCS, Baltimore, Maryland**

To: Director, Baltimore Office of Healthcare Inspections (54BA)

Director, Management Review Service (VHA 10AR MRS OIG Hotline)

1. I have reviewed the draft report and concur with the VA Maryland HCS' planned actions for improvement.

2. If you have any questions please contact Jeffrey Lee, VISN 5 Quality Management Officer at 410-691-7816.

Fernando Rivera
Director, VISN 5 (10N5)

Appendix C

System Director Comments

Department of Veterans Affairs **Memorandum**

Date: June 11, 2014

From: Director, VA Maryland Health Care System, Baltimore, MD (512)

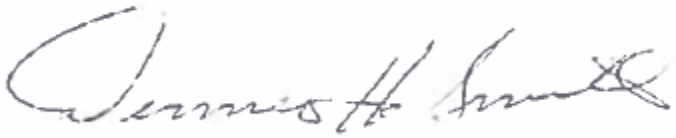
Subject: **Healthcare Inspection – Alleged Mismanagement in the Cardiac Catheterization Laboratory, VA Maryland HCS, Baltimore, Maryland**

To: Director, VA Capital Health Care Network (10N5)

1. I have reviewed the draft report and concur with the OIG Recommendations.

2. Thank you for the opportunity to review the draft report. Our corrective actions have been established with planned completion dates as detailed in the attached report.

3. If you have any further questions, please contact me at 410-605-7016.



Dennis H. Smith

Comments to OIG's Report

The following Director's comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

Recommendation 1. We recommended that the System Director ensures that nurse staffing is appropriate for the volume and types of procedures performed in the cardiac catheterization laboratory and that the requisite nurse competencies are maintained.

Concur: Yes

Target date for completion: Completed

Facility response: The Cardiac Catheterization Laboratory continues to adhere to the current practice of utilizing two Registered Nurses for all procedures within the department. Nursing staff that assist, to cover absences, in this department from other areas are competent to practice in the Cardiac Catheterization Laboratory. These nursing staff successfully completed a Cardiac Catheterization competency prior to working in the Cardiac Catheterization Laboratory and will successfully complete a yearly competency in order to practice in this area.

Recommendation 2. We recommended that the System Director ensures that the policies and procedures regarding the rapid response team, code blue team, and Anesthesia Services are updated as needed to reflect desired practices for managing cardiac catheterization laboratory emergencies.

Concur: Yes

Target date for completion: July 31, 2014

Facility response: The policy for the Rapid Response Team and the Code Blue Team is being combined into the VAMHCS Policy "Medical Emergency Response Teams." The Medical Emergency Response Team responds to both a Rapid Response and a Code Blue. The Anesthesia Service is a member of the Medical Emergency Response Team at Baltimore.

Recommendation 3. We recommended that the System Director ensures that the staff receive training on updated policies and procedures regarding the rapid response, code blue team and Anesthesia Services.

Concur: Yes

Target date for completion: July 31, 2014

Facility response: The VAMHCS Policy "Medical Emergency Response Teams" will be published in July 2014. The plan to educate VAMHCS staff on this new policy is:

a. Each Cardiac Catheterization Lab staff member will review and initial the policy.
b. The roles and responsibilities contained within the policy will be discussed at the Staff Meeting scheduled in July and August 2014.
c. Draft policy will be presented in the Executive Committee of the Medical Staff on June 27, 2014 by the Acting Director, Center for Performance.

Appendix D

OIG Contact and Staff Acknowledgments

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Appendix E

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